

REMARKS

Claims 1,5-12,17,18,24,29,30,36-39 and 67-72 are pending.

Claims 2-4, 19-23, 25-28, 40-48, 58-65 and 73-80 have been withdrawn.

Claims 13-16, 17, 18, 24, 19,31-35, 49-57, and 66 are cancelled.

Support for the “fabric” amendment to claims 1, 30, 36 and 67 is found in the as-filed application at 14, line 23-29.

The abstract stands objected to as being in claim format, rather than in narrative form. Applicants have submitted herewith an amendment to the abstract that places the abstract in a narrative form.

Claim 72 stands rejected under 35 USC 112, second paragraph as being indefinite. The Examiner takes the position that, in line 1, the phrase “conformable portion” lacks proper antecedence. Applicants have submitted herewith an amendment to claim 72 that replaces “conformable” portion, with –end- portion, and submits that proper antecedent basis therefore is provided in independent claim 67.

Claims 1,5-7, 11,12,17,18,24,30,36-39, 67,68 and 72 stand rejected under 35 USC 102 as being anticipated by US Patent No. 6,090,998 (“Grooms”).

Applicants submit that the as-amended claims are not anticipated by Grooms. Grooms is directed to “a novel unitary bone implant”. See Summary of the Invention in Grooms. This implant is made by demineralizing an intermediate portion of the bone segment. As Grooms is directed to a ligament having a flexible, demineralized section derived from bone, Grooms does not disclose an implant having a fabric component, as

provided by the present claims. Since the present claims are not anticipated by Grooms, the present anticipation rejection over Grooms must be withdrawn.

Moreover, it appears Grooms is directed solely at implants made from natural bone materials:

This invention provides a biologically acceptable ligament, tendon, support or other implant for replacement of damaged ligaments, tendons, vertebral disk and the like, wherein there is a need for an implant having both a rigid machined portion or segment as well as a flexible demineralized portion or segment (col. 2, lines 41-46)(emphasis supplied)

Since Grooms appears directed to the manufacture and design of bone implants, there is nothing in Grooms that would provide any motivation to the skilled artisan to replace the demineralized bone implant portion of Grooms with non-bone materials such as fabrics. Therefore, Grooms can not render the present invention obvious, even in combination with other references.

Claims 1,5-12,17,18,24,29, 30,36-39, 67-72 stand rejected under 35 USC 102 as being anticipated by US Patent No. 5,269,783 ("Sanders").

Applicants respectfully traverse. In order to anticipate a claim, a prior art reference must teach every limitation in that claim. In this respect, Applicants note that the present claims all recite an intervertebral connection system having a "ligament comprising a "fabric" and a "bone fastener."

In contrast, Sanders discloses a device comprising two anchoring members suitable for anchoring soft tissue and connected by a suture:

The present invention provides a novel device for repairing torn tissue and muscle such as the menisci in the knee joint which expedites the surgical process and facilitates complete healing of the tear. (col. 1, lines 65-68)(emphasis supplied)

Since the tissue penetrated by the anchoring device of Sanders is relatively soft, the anchoring devices of Sanders need not be adapted for fastening to bone. Accordingly, the anchoring members of Sanders may be made of a somewhat compliant material having a shape and a hardness suitable for anchoring to a relatively soft tissue, but which would deform and/or crumple when inserted into a recess in a bone, thereby making the anchor predisposed to pull out. Simply, Sanders does not disclose, nor appreciate any need for, an anchor adapted for fastening to bone.

In contrast, the present invention requires a bone fastener. Bone fasteners are made of materials and are shaped for anchoring to bone and for providing a secure fit therein. The needs of the bone fastener to be adapted to resist pullout and provide a secure fit are discussed at pages 17, third full paragraph, and page 18, third and fourth full paragraph, of the as-filed application.

As Sanders is directed to a soft tissue repair device, Sanders does not disclose an implant having a "bone fastener" component, as provided by the present claims. Since the present claims are not anticipated by Sanders, the present anticipation rejection over Sanders must be withdrawn.

Moreover, since Sanders appears directed to the manufacture and design of soft tissue anchors for the knee meniscus, there is nothing in Grooms that would provide any motivation to the skilled artisan to replace the soft tissue anchor with a bone fastener. Therefore, Sanders can not render the present invention obvious, even in combination with other references.

In addition, the present invention requires a ligament component comprising a fabric. Sanders does not disclose a ligament made of fabric, but merely a suture. As discussed in the as-filed application at page 3, line 28, a suture can not be considered to be a ligament made of fabric suitable for use in an intervertebral connection system:

The use of sutures as a ligament-bone fastener connection means is disadvantageous for many reasons. For example, because sutures are

typically weak, they are prone to failure, thereby risking detachment of one end of the ligament in the vicinity of the aorta.

Since Sanders does not disclose a ligament comprising a fabric, nor a ligament adapted for use in an intervertebral connection system, the present claims are not anticipated by Sanders, and so the present rejection over Sanders must be withdrawn.

Lastly, notes that claims 78-80 (method claims) have been withdrawn by the Examiner. However, the undersigned has recently noted that, although the Jan. 14, 2003 Election Requirement found that, overall, the Group I claims were readable on these claims 78-80, none of the species I-VI of that general Group I set were identified by the Examiner as reading on those method claims 78-80. Since it appears that, upon election of a subspecies, Applicants could not have these method claims considered in the present prosecution, Applicants would like the Examiner to reconsider the withdrawal of these method claims from the present prosecution.

Applicants believe that inventorship remains the same as in the as-filed case.

In a telephone interview with the Examiner, it was agreed that Applicants would provide a Declaration under 37 CFR 1.131 in order to antedate US Published Patent Application US 2002/0120270 ("Trieu"), filed in the USPTO on Feb.26, 2002, and which claims priority from US Provisional patent Application No. 60/272,114, filed on Feb. 28, 2001. Enclosed herewith is a Declaration of Hassan Serhan under 37 CFR 1.131, in which Dr. Serhan states that the present invention was conceived by January 8, 2001. Applicants submit that the Declaration of Hassan Serhan under 37 CFR 1.131 is sufficient to antedate the earliest possible date of Trieu.

In addition, please provide any extensions of time which may be necessary and charge any fees which may be due to Deposit Account No. 10-0750, but do not include any payment of issue fees.

Should there be any remaining or further questions, the Examiner is requested to place contact the undersigned directly.

Respectfully submitted,

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